IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,	)	
Plaintiffs,	)	C.A. No. 17-1407-CFC-SRF (CONSOLIDATED)
v.	)	
AMGEN INC.	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF GENENTECH'S MOTION TO DISMISS AMGEN'S FIFTEENTH COUNTERCLAIM AND STRIKE ITS FIFTEENTH AFFIRMATIVE DEFENSE

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Genentech filed this suit in 2017 seeking legal, equitable, and declaratory relief for Amgen's infringing manufacture and sale of Mvasi, its generic version of Genentech's best-selling cancer therapy Avastin.

Last month the Court denied Amgen leave to add a counterclaim accusing Genentech of inequitable conduct in the prosecution of one of the patents—U.S. Patent 8,574,869 ("Kao")—Amgen is accused of infringing. D.I. 628. The Court found that "Amgen unduly delayed by waiting until September 2019 to seek leave to add" the inequitable conduct claim. *Id.* at 3. The Order did not address Genentech's additional argument that Amgen's proposed amended was futile and should be denied on that basis.

A week later Genentech filed a Second Amended Complaint. Although none of Genentech's amendments changed the theory of its case regarding the Kao patent, Amgen's Second Amended Answer, Affirmative Defenses, and Counterclaims nevertheless includes the same inequitable conduct theory (as its Fifteenth Affirmative Defense and counterclaim Count 15) the Court previously denied leave to add. D.I. 648.

The Court should again reject Amgen's efforts to add this claim to the litigation. Rule 15 does not permit Amgen to add a new counterclaim on subject matter that has not changed from the original complaint. And even if it did,

Amgen's theory of inequitable conduct is meritless.

ARGUMENT

I. RULE 15 DOES NOT AUTHORIZE THE INEQUITABLE CONDUCT THEORY THE COURT HAS ALREADY DEEMED UNTIMELY.

Amgen apparently relies on Fed. R. Civ. P. 15 as authority for filing an inequitable conduct claim the Court less than a month earlier expressly disallowed.

Rule 15(a) permits a party to file "any required response to an amended pleading . . . ." Recent decisions in this District do not interpret Rule 15(a) as authorizing new allegations that do not qualify as "required response[s]" to an amended complaint. Instead, they construe Rule 15(a) as permitting amendments without leave of Court *only* when "the breadth of the changes in the amended response . . . reflect the breadth of the changes in the amended complaint." *Teva Pharm. USA, Inc. v. Forest Labs., Inc.*, 2016 WL 7325511, at *1 n.1 (D. Del. June 16, 2016) (quoting *Elite Entm't, Inc. v. Khela Bros. Entm't*, 227 F.R.D. 444, 446 (E.D. Va. 2005); *Sirona Dental Sys., Inc. v. Dental Imaging Techs. Corp.*, 2012 WL 3929949, at *3 (D. Del. Sept. 10, 2012). Amendments that do not change the breadth of the complaint do not "throw the door open to entirely new claims and defenses." *Sirona*, 2012 WL 3929949, at *3.

This interpretation of Rule 15(a), which courts characterize as a "moderate approach" to the scope of permitted amendments, is the "majority" and the "most sensible" view, and is supported "by the weight of authority, from both judges and

commentators." *Teva*, 2016 WL 7325511, at *1 n.1; *see also, e.g.*, *Patel v. Pandya*, 2016 WL 3129615, at *2 (D.N.J. June 2, 2016) (explaining "the moderate approach" and noting that it is "favored by commentators as well"); *Slim CD, Inc. v. Heartland Payment Sys., Inc.*, 2007 WL 2459349, at *6 (D.N.J. Aug. 24, 2007); *Upek, Inc. v. Authentec, Inc.*, No. 10-424-JF (PVT), 2010 WL 2681734, at *3 (N.D. Cal. July 6, 2010). The Federal Circuit has approved of the moderate approach to reject efforts "to expand the breadth of [] affirmative defenses or counterclaims." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1359-60 (Fed. Cir. 2011) (applying Second Circuit law).[1]

Here, Genentech's Second Amended Complaint adds nothing that justifies the addition of an entirely new defense asserting a factual theory on which no

[1] Genentech is mindful of the Court's ruling in the related case concerning Genentech's Herceptin product authorizing the addition of Amgen's Kao inequitable conduct theory in response to an amendment adding a post-launch claim for damages. Civ. No. 18-924, D.I. 507. The Court cited *Standard Chlorine of Del., Inc. v. Sinibaldi*, 1995 WL 562285, (D. Del. Aug. 24, 1995) for the proposition that "[i]t has long been the rule in this district that in answering an amended complaint the defendant is free to answer not simply the amendments, but the new complaint, as if answering an original complaint." *Id.* at 2. Genentech respectfully submits that *Standard Chlorine* overstates the extent of the authority in this District. Genentech has been able to find only five prior cases in Delaware squarely addressing this issue. The only two Delaware cases decided in the last decade, *Teva*, 2016 WL 7325511, and *Sirona*, 2012 WL 3929949, both favored the moderate approach. The three cases that adopted a more "permissive approach" were all decided more than twenty years ago, and none of them appear to address the impact of a missed deadline in a scheduling order, much less a situation where—as in this case—the amended response includes defenses that the Court has already held could have been pursued prior to that deadline.

discovery has occurred. Recognizing the need to prepare this case for trial, the Court recently rejected Genentech's effort to add another accused product to its assertions of Kao infringement, holding that "[t]o expand the scope of the case after two years of intense litigation . . . would undermine the Court's previous efforts to drive the case to a reasonable and efficient conclusion." D.I. 629 at 5. At this late juncture, there is no basis in law or fair play to preclude Genentech from pursuing new infringement allegations in this case yet permit Amgen to use the filing of Genentech's amended complaint (which, per the Court's ruling, excluded allegations against a different product) as a basis to inject wholly new factual and legal theories into the case.

That Amgen seeks to do so months after the deadline for fact discovery has passed, and after this Court found that "Amgen unduly delayed by waiting until September 2019 to seek leave to add" the defense, makes it all the more inappropriate. Were Amgen's eleventh-hour allegation allowed, Genentech may be deprived of the opportunity to take discovery necessary to defend against it, including deposition and document discovery from Amgen scientists (and others who have previously praised the Kao inventors' work) regarding the data and references at issue, and Amgen's analysis of them. This is the sort of prejudice against which Rule 15 protects. Consistent with the weight of authority interpreting Rule 15, Amgen's attempt to add its new counterclaim should be

rejected.

II. AMGEN FAILS TO PLEAD A VIABLE THEORY OF INEQUITABLE CONDUCT.

Amgen's theory of inequitable conduct is legally deficient in any event. It focuses on Example 8 in Kao, specifically, the patent's characterization of an experiment using air sparging to prevent "reduction" (*i.e.*, breakage) of the disulfide bonds that hold antibodies together. Unlike the typical inequitable conduct case, *see*, *e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (*en banc*), Amgen does *not* accuse Genentech of deliberately concealing references from the Patent Office. Rather, Amgen contends that Example 8 omitted data that were included in the authors' subsequent publication of their research. Although Amgen's pleading is lengthy (due largely to redundancy and the number of people Amgen is accusing), the allegations boil down to the assertion that this data disproves the inventors' claim to have discovered a method to prevent disulfide bond reduction and therefore should have been provided to the Examiner for consideration.[2]

There is a fundamental problem with Amgen's theory: It is undisputed that

[2] *See, e.g.*, D.I. 648 ¶ 205 (listing the following "affirmative misrepresentations": "That Example 8 demonstrates the prevention of the reduction of disulfide bonds over 36 hours"; "That the nitrogen sparge control only shows a decrease in the purported percent of intact antibody over the entire 36-hour time course of Example 8; and "The lack of identification of the cause of the approximately 85% intact antibody in the initial solution at t=0 hr HCCF Hold Time.")

the article that included the data the patent application omitted—"Trexler-Schmidt 2010"[3]—*was* provided to and considered by the Examiner during prosecution. *See* D.I. 648 ¶¶ 75, 216 (acknowledging that Trexler-Schmidt 2010 was "submitted [in] an Information Disclosure Statement dated May 24, 2013"). Where the examiner had the opportunity to review the information at issue and accept or reject the applicant's interpretation of it, there can be no inequitable conduct as a matter of law. *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). An "applicant is free to advocate its interpretation of its claims." *Id.* (affirming summary judgment of no inequitable conduct and an award of attorneys' fees incurred in defending the charge); *Rothman v. Target Corp.*, 556 F.3d 1310, 1329 (Fed. Cir. 2009); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). This is so because where the Patent Office has the underlying information, it also has "discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." *Rothman*, 556 F.3d at 1329; *see also Akzo N.V. v. ITC*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("The examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him").

An instructive example is *Sepracor Inc. v. Teva Pharm. USA, Inc.*, 2010 WL

[3] Ex. 1 (Trexler-Schmidt et al., *Identification and Prevention of Antibody Disulfide Bond Reduction During Cell Culture Manufacturing*, 106 Biotechnology & Bioengineering 452 (2010).

2326262 (D.N.J. June 7, 2010). The patentee there submitted data, declarations, and attorney argument to support its assertion that the claimed isomer possessed the "surprising and expected property" of being less toxic than similar prior-art compounds. *Id.* at *2. The defendant alleged that the patentee had committed inequitable conduct by "mischaracterizing data relating to an 'acute oral toxicity test in mice' that was supplied to the PTO." *Id.* at *3. The court rejected those allegations, concluding that the defendant's "inequitable conduct claim must be dismissed . . . because the oral toxicity study results were before the examiner, and he was entitled to reach his own conclusions on the study . . . . Therefore, any mischaracterization of the data would not rise to the level of inequitable conduct." *Id.* at *6.

Amgen's allegations fail for the same reason. Amgen does not even attempt to allege that Genentech deliberately concealed information in its possession from the Patent Office. Amgen's claim relies instead on a purported inconsistency between Example 8 of the Kao patent and the description of the same experiment in Trexler-Schmidt 2010, a peer-reviewed publication *Amgen admits was provided to the Patent Office during prosecution of Kao*.[4] Amgen contends that Genentech

[4] Amgen cannot take the position that the examiner somehow overlooked Trexler-Schmidt 2010. The examiner is "presumed" to have appropriately considered the evidence of record. *See Applied Mats., Inc. v. Adv. Semiconductor Mats. Am. Inc.*, C.A. No. 92-20643-RMW, 1994 WL 270714, at *3 (N.D. Cal. Apr. 19, 1994) (citing *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990)).

mischaracterized the results of Example 8, and failed to alert the Patent Office to information that Amgen says would have established that the claimed air sparging method does not actually prevent the reduction of disulfide bonds. But Genentech affirmatively disclosed the supposedly contrary data when it provided Trexler-Schmidt 2010 to the Examiner, who was free to consider it and reach an independent conclusion as to what the data showed.

The fact that the inventors included this data in a publicly available, peer-reviewed article touting their invention also renders implausible any suggestion they believed their invention was a sham. If the inventors knew the data in Trexler-Schmidt 2010 completely undermined their invention, as Amgen claims, why would the inventors provide the same data to reviewers—and then to the Patent Office?

This is not to say that attorney argument can never cross the line into affirmative misrepresentation. *See, e.g.*, *Rothman*, 556 F.3d at 1328 (noting that "the law prohibits genuine misrepresentations of material fact"). A patentee may not, for example, make false representations as to facts where "the essential information [lay] uniquely within [the patentee's] control." *Exergen*, 575 F.3d at 1330. But Amgen cannot levy such an accusation here, where the information from Trexler-Schmidt Amgen asserts to be inconsistent was before the Examiner, rather than uniquely within Genentech's control.

Amgen's counterclaim does not even rest on any actual statements that Genentech made to the Patent Office. Consider Amgen's accusation that the Kao inventors and Genentech's outside prosecution counsel misrepresented that "the nitrogen sparge control only shows a decrease in the purported percent of intact antibody over the entire 36-hour time course of Example 8." *E.g.*, D.I. 648, ¶64. This supposed "statement" is not a quote from the patent or any prosecution document. Amgen cannot identify a single instance in which any of the individuals it accuses of inequitable conduct stated that the nitrogen sparge experiment only shows a decrease in the percentage of intact antibody over the entire 36-hour period.[5] Thus, even were Amgen's characterizations of Example 8 scientifically accurate it cannot establish that any of individuals it accuses made the kind of misleading statements that could be actionable under the law. At best, Amgen has offered bare assertions about why *Amgen* thinks Example 8 of the Kao Patent shows the inventors' claimed method does not prevent reduction. That is not

[5] Regarding the nitrogen sparged sample, the written description states "the antibody reduction event continued as measured at 2 hr (28% 150 kDa peak) and 6 hr (5% 150 kDa peak)." Kao Patent at 56:12-13. Data shown in Figure 20 is also consistent, as indicated by the filled squares representing the percent intact antibody at 2 and 6 hours. Kao Patent at FIG. 20. No data past the six-hour time point in the nitrogen sparge sample was discussed in Example 8, let alone included in Figure 20. The written description likewise contains no discussion of percent intact antibody in the nitrogen sparged sample past the 6-hour time point. Thus, applicants at most represented that the nitrogen sparge control shows a decrease in percent intact antibody over 6 hours.

enough to support an inequitable conduct claim.

The Federal Circuit has long recognized "the habit of charging inequitable conduct in almost every major patent case" is "an absolute plague." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The court has emphasized the need to deter frivolous accusations that would otherwise "hurt the reputations of those being attacked," "lest inequitable conduct devolve into 'a magic incantation to be asserted against every patentee.'" *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1331 (Fed. Cir. 2009) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997) (Alito, J.); *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)). Amgen's theory of inequitable conduct claim is the sort of baseless, scattershot accusation of wrongdoing the Federal Circuit has sought to foreclose. Its allegations should be dismissed.

CONCLUSION

For the foregoing reasons, Genentech respectfully requests that the Court strike the portion of Amgen's Fifteenth Affirmative Defense directed to the Kao Patent under Rule 12(f) and strike, or dismiss under Rule 12(b)(6), Count 15 of Amgen's counterclaims.

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Respectfully Submitted,

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